## REMARKS

Claims 31, 34-40, 46-48, 50, 53-56, 59, and 62-65 are pending. By virtue of this response, claims 31, 40, 50, and 56 are amended. Therefore, claims 31, 34-40, 46-48, 50, 53-56, 59 and 62-65 are presently pending. No new matter is added

### I. Interview Summary

Applicant thanks the Examiner for the telephonic interview conducted October 22, 2010. In attendance was Examiner Danega, Supervisor Hindenburg, and Applicant's representatives Brian Ho and Benno Guggenheimer.

During the interview, Applicant's representatives discussed claim 31 with respect to the reference electrode described in Pearlman. In particular, Applicant's representatives explained how Pearlman couldn't be used to isolate the impedance of the skin directly under a selected test electrode. Examiner and Supervisor agreed that the claims overcome the Pearlman reference. However, Examiner maintained the finality on the rejection under the cited art in combination with Masuo.

Examiner agreed to consider arguments and amendments submitted in an after final response.

### II. Claim Rejections Under 35 USC §103

Claims 31, 34-36, 39-40 and 46-48, 50, 53-56, 59, and 62-65 stand rejected under 35 U.S.C. 103(a) as purportedly being unpatentable over Bloom et al. (U.S. 6,963,772, hereinafter "Bloom") in view of Pearlman (U.S. 6,308,097, hereinafter "Pearlman"), Masuo (U.S. 2003/0176808, hereinafter "Masuo"), and Kenan et al. (U.S. 6,788,966 hereinafter "Kenan").

Applicant submits that none of the references teach a three-electrode system as recited in claim 31. Applicant further submits that modifying Bloom, Pearlman, and Masuo to use a three-electrode configuration would render each of the references unsatisfactory for its intended purpose.

### A. The References Fail to Disclose or Suggest All Limitations of the Rejected Claims

The system recited in claim 31 monitors changes in the surface of a skin wound by measuring an electrical characteristic of the top layers of the skin (e.g., the epidermis). As

recognized in the specification, "when the stratum corneum [the outer portion of the epidermis] is punctured or abraded, the measured low-frequency impedance at the site will be dramatically reduced." (Specification at ¶ 0032.)

The system recited in claim 31 monitors changes in the surface of the skin using a three-electrode configuration that measures an electrical characteristic (e.g., impedance) of the skin tissue immediately underlying a test electrode.

Claim 31 recites, in relevant part:

> calculating the electrical characteristic of the tissue immediately under each currently selected test electrode as a function of the voltage difference between the currently selected test electrode and at least one reference electrode, adjacent to the currently selected test electrode, the voltage difference being measured while passing the electrical alternating current between each currently selected test electrode and the at least one further electrode [applied to the skin at a location away from the wound].

(Emphasis added.) Discussed in more detail below, the three-electrode configuration recited in claim 31 provides a distinct advantage in that the measurement isolates the impedance of the tissue immediately below the selected test electrode. (*See, e.g.*, specification at ¶ 0070.)

An example of the three-electrode system recited in claim 31 is depicted in Fig. 6 of the specification, reproduced below.

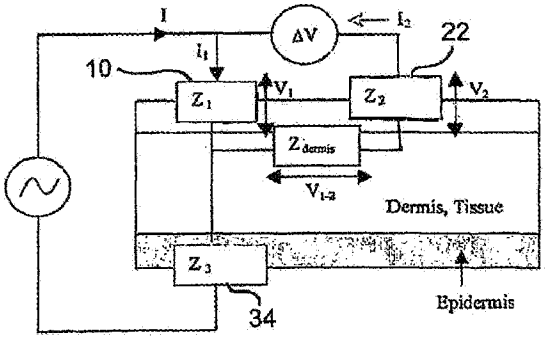



Fig. 6

As shown in Fig. 6, an electrical alternating current is passed between the currently selected test electrode (item 10) and on further electrode (item 34), applied to the skin at a location away from the wound. While the current is being applied, a voltage difference is measured between the

currently selected test electrode (item 10) and the reference electrode (item 22), adjacent to the currently selected test electrode. Applicant submits that the cited reference references, alone or in combination, do not disclose the three electrode system recited in claim 31.

As described in the specification, the three-electrode configuration provides a distinct advantage in that the measurement isolates the electrode-skin impedance ($Z_1$). As explained in paragraph [0070]:

> As the voltmeter used contains an instrumentation amplifier with an extremely high input impedance, the current $I_2$ flowing through it (and the impedances $Z_{dennis}+Z_2$) will be negligibly small. The voltages $V_{1-2}$ and $V_2$ measured across the tissue impedance and the site below the reference electrode, respectively, will therefore also be negligible. As a result, the measured voltage difference $\Delta V$ is solely equal to the voltage drop V, across the test electrode-skin impedance under investigation.

Thus, the electrode-skin contact impedance ($Z_1$) can be isolated by passing a current through the currently selected test electrode (item 10), while measuring the voltage between the currently selected test electrode (item 10) and an adjacent reference electrode (item 22).

Applicant submits that the cited reference references, alone or in combination, do not disclose the three electrode system recited in claim 31. Furthermore, because the references do not disclose or suggest the limitations of the three-electrode system, the two-electrode or four-electrode prior art techniques cannot accomplish the desired isolation of the electrode-skin impedance.

***Two-Electrode Methods of Pearlman and Bloom***

Both Pearlman and Bloom describe two-electrode measurement systems for monitoring a portion of tissue interposed between an electrode pair. In both Pearlman and Bloom, a current is passed through the interposed tissue so that the impedance of the tissue (*e.g.*, underlying the epidermis) can be measured. As a result, the current loop includes both electrode-to-surface interfaces and the tissue between the electrodes. Because the same electrodes applying the current are used to measure the impedance, the measured impedance necessarily includes everything in the current loop (*i.e.*, the contact impedance at both electrodes and the impedance of the intervening tissue). Both Pearlman and Bloom lack a voltage measurement taken between a current-carrying electrode and an adjacent reference electrode. Lacking the required structure, it is not possible to use the two-electrode techniques of Bloom and Pearlman to isolate an electrode-to-skin impedance

(*i.e.*, "an electrical characteristic of tissue immediately underlying [the] test electrode") as done using the three-electrode configuration recited in claim 31.

In the Office Action, the Examiner admits, and the Applicant agrees that Bloom does not disclose a reference electrode, as recited in claim 31. (Office Action at 3.) Also, during the interview conducted October 23, 2010, Examiner agreed that Pearlman also does not disclose this element. As discussed in the interview, while Pearlman does mention a "reference electrode," the reference electrode is used to merely provide an alternate two-electrode measurement. For example, Pearlman's reference electrode can be used as an alternative to the array of emitting electrodes. (Pearlman at 7:26-35.) Pearlman describes that a measurement can be taken using the reference electrode (instead of the array of electrodes) to establish a baseline or overall tissue impedance. (Pearlman at 19:57-20:3.) Because this is also a two-electrode measurement, the impedance necessarily includes the contact impedance of both electrodes and the impedance of the tissue interposed between the electrodes.

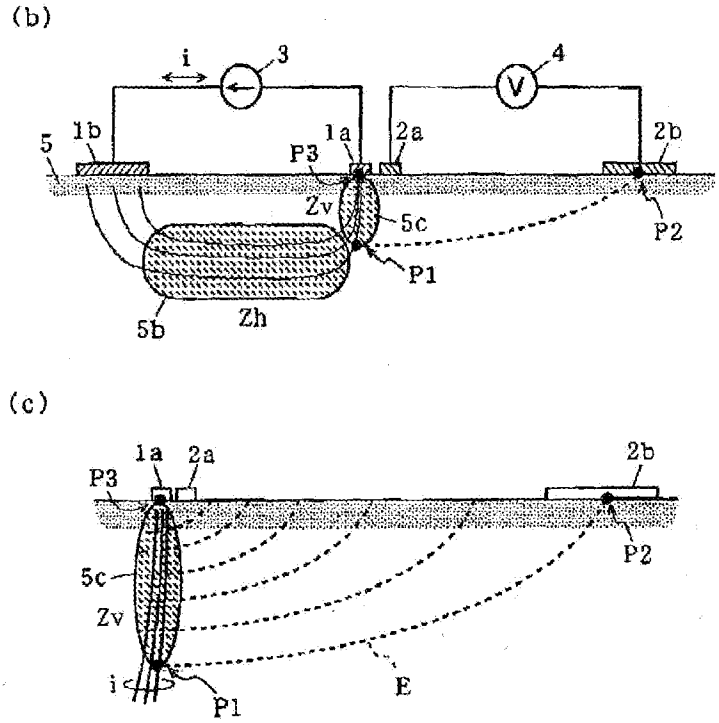
Therefore, the two-electrode techniques described in Pearlman and Bloom do not disclose or suggest a measurement "calculating the electrical characteristic of the tissue under each currently selected test electrode as a function of the voltage difference between the currently selected test electrode and at least one reference electrode, adjacent to the currently selected test electrode," as recited in claim 31.

***Four-Electrode Method of Masuo***

Masuo does not remedy the deficiencies in the other two references. In general, Masuo uses a four-electrode technique to measure properties of deep (subcutaneous) tissue, such as the quantity of fat at a depth below the skin. (Masuo at ¶ 0011.) The four-electrode system of Masuo is designed to measures the impedance of a region of subcutaneous tissue starting a point (P3) just below the surface of the skin to another point (P1) some depth into the tissue. (*See, e.g.*, Masuo Figs. 1 and 3, below). In contrast to the three-electrode configuration of claim 31, Masuo aims to eliminate impedance contributions due to the skin-to-electrode interface. (Masuo at ¶ 0005.). Accordingly, Masuo's intent is to eliminate the very characteristic measured by the claimed system.

In reference to the first embodiment (Fig. 1), Masuo uses a pair of current-carrying electrodes (1a and 1b) to induce a current flow penetrating the tissue of the body. A separate pair of

measurement electrodes (2a and 2b) are used to measure the impedance of the subcutaneous tissue below one of the measurement electrodes ($Z_v$). (Masuo at ¶ 0081.)



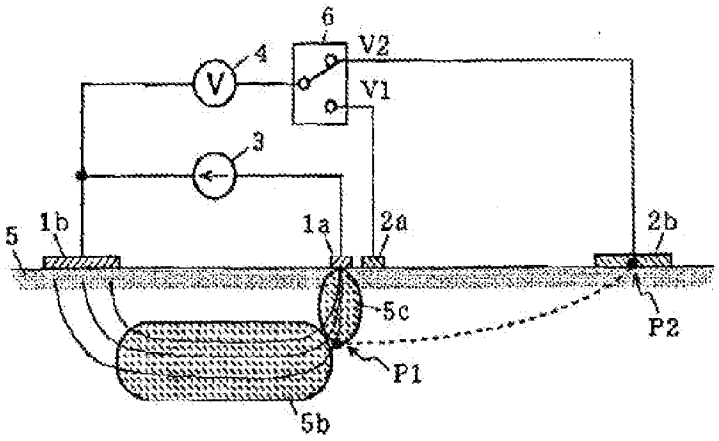

Note that there is virtually no current passing through the measurement electrodes (2a and 2b) due to the high impedance of the voltmeter (item 4). Because there is no current passing through the electrode-skin interface for measurement electrodes 2a and 2b, Masuo's Fig. 1 embodiment does not measure any electrode-skin impedance. Also note that the measurement electrode (2a) estimates the voltage at point P3 by measuring the voltage of an equipotential on the surface of the skin. Because there must always be at least some distance between the current-carrying electrode (1a) and the measurement electrode (2a), the point P3 must necessarily be located at least some distance below the surface of the skin. Therefore Masuo's Fig. 1 embodiment cannot be used to measure an electrical characteristic immediately below a selected test electrode, as done the three-electrode system of claim 31. This is in fact desirable as Masuo is concerned with the impedance of subcutaneous fat tissue, which is more accurately measured when the impedance contribution due to the electrodes (and presumably skin) is eliminated. (*See, e.g.*, Masuo at ¶ 0005.)

In rejecting claim 31, Examiner references Masuo Fig. 3, which depicts an alternative arrangement of the four-electrode system discussed above. In Fig. 3, a measurement is made by subtracting the voltage between each of the measurement electrodes (2a and 2b) and a remote current-carrying electrode 1b. Similar to the embodiment in Fig. 1, the measurement resulting from the subtraction in Fig. 3 estimates the impedance of the tissue located below the surface of the skin (5c) without including the impedance of the electrodes or electrode-to-skin interface.

The arrangement depicted in Masuo Fig. 3 does not teach the three-electrode system of claim 31. Specifically, Masuo does not disclose a "voltage difference between the currently selected test electrode and at least one reference electrode, adjacent to the currently selected test electrode." One of ordinary skill would understand that "adjacent" means next to, very near, immediately preceding or immediately following.[1]

Assuming, for the sake of argument, that Masuo's current carrying electrode (1a) is analogous to the "currently selected test electrode" and one of Masuo's measurement electrodes (either 2a or 2b) is analogous to the "reference electrode" recited in claim 31. Reference is made to Fig. 3 of Masuo, reproduced below.

Fig. 3




In Masuo, the voltage (either V1 or V2) is measured between the further current-carrying electrode (1b) and one of the measurement electrodes (either 2a or 2b). Masuo explains that the

[1] *See*, "adjacent" as defined in Merriam Webster on-line (www.merrian-webster.com/dictionary/adjacent) and Cambridge Dictionaries Online (http://dictionary.cambridge.org/dictionary/british/adjacent).

further current-carrying electrode is "provided at a third part on the surface of the living body, apart from the first part [2a] and second part [2b]." (Masuo at ¶ 0031.) Masuo further explains that a separation is necessary to allow the current supplied by the current carrying electrodes (1a and 1b) to penetrate the tissue at a suitable depth. (Masuo at ¶¶ 0028, 0032.) Furthermore, whichever measurement electrode (either 2a or 2b) is selected to be the "reference electrode," there is always another electrode (1a) separating the current-carrying electrode and the measurement electrode. Because the electrodes used to measure the voltage (1) must be set apart a distance and (2) are always separated by another, intervening electrode, Masuo does not disclose or suggest a voltage measurement taken between adjacent electrodes. (*i.e.*, between electrodes that are next to, very near, immediately preceding or immediately following each other.) Therefore, the four-electrode technique described in Masuo does not disclose or suggest a measurement "calculating the electrical characteristic of the tissue under each currently selected test electrode as a function of the voltage difference between the currently selected test electrode and at least one reference electrode, adjacent to the currently selected test electrode," as recited in claim 31

This distinction is meaningful because Masuo's voltage measurement (V1 or V2) cannot isolate the electrode-to-skin contact impedance, as done using the three-electrode technique recited in claim 31. As shown in Fig. 3 of Masuo, the non-adjacent electrode configuration results in significant portions of the subcutaneous tissue being included in the current loop. Thus, the voltage measurement (either V1 or V2) necessarily includes impedance contributions from the subcutaneous tissue region 5b, at least a portion of the tissue region 5c in addition to the electrode-to-skin impedance at electrode 1b. Furthermore, Masuo explains that the voltage V1 should be subtracted from voltage V2 resulting in a measurement that specifically excludes impedance contributions from the electrode-to-skin contact. (Masuo at ¶¶ 0031, 0086.) Therefore, Masuo's four-electrode system (lacking an adjacent reference electrode) also fails to isolate the electrode-to-skin contact impedance as done using the three-electrode technique recited in claim 31.

***Summary***

As described above, Bloom, Pearlman, and Masuo fail to disclose or suggest all of the limitations of claim 31. Moreover, Kenan, describing a hand-held device having an array of electrodes, fails to remedy the deficiencies in the other references. Therefore, claim 31 is not obvious over the cited reference.

Independent claim 50 also recites, "calculating the electrical characteristic of the tissue immediately under each currently selected test electrode as a function of the voltage difference between the currently selected test electrode and at least one reference electrode adjacent to the currently selected test electrode." For at least the reasons given above with respect to claim 31, the references also fail to render obvious claim 50. Claims 34-37, 39, 40, 46-48, 53-56, 59, and 61-65 are also not rendered obvious for at least the reason that they depend from allowable independent claims 31 and 50.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom as applied to claims 31 above, and further in view of Cudahy et al. (U.S. 5,184,620, hereinafter "Cudahy"). Applicant submits that Cudahy also does not remedy deficiencies in the other references. Therefore, claim 38 is also not obvious for at least the reason that it depends from allowable claim 31.

Accordingly, Applicant respectfully requests that the rejection of claims 31, 34-40, 46-48, 50, 53-56, 59, and 62-65 be withdrawn and the claims allowed.

## B. Modifying Bloom, Pearlman, and Masuo to Use a Three-Electrode Configuration Would Render Each Reference Unsatisfactory for Its Intended Purpose.

If a proposed modification renders the prior art unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification. (MPEP 3143.01 V.) Applicant submits that modifying Bloom, Pearlman, and Masuo to use the three-electrode configuration, recited in claim 31, would render each of the references unsatisfactory for its intended purpose.

In general, Bloom uses two-electrode pairs to monitor fluid accumulation within a portion of tissue to track, for example, swelling (e.g., hematoma) or presence of a foreign body in the tissue. (Bloom at 2:63-67; 4:53-64; 6:47-53.) In Bloom, the electrodes are preferably placed across the entire tissue under investigation. (Bloom at 9:8-17.) By passing a current through the two-electrode pair, the impedance of the interposed tissue can be measured. As described above, using the three-electrode configuration recited in claim 31 (including an adjacent, reference electrode), the resulting system isolates the electrode-to-skin impedance and eliminates or minimizes contributions due to the impedance of tissue interposed between the electrodes. Assuming that it is even possible to modify Bloom to use a three-electrode system, such a measurement would provide no information about the amount of fluid in the interposed tissue, and therefore would not allow Bloom to monitor the swelling or presence of a foreign object in the tissue. As such, the modification would render Bloom unsatisfactory for its intended purpose.

Similarly, Pearlman uses two-electrode pairs to investigate the presence of a tumor or malignant tissue deep in the body tissue. (Pearlman at 4:3-22.) Similar to Bloom, the technique in Pearlman measures the impedance of tissue interposed between electrode pairs. As described above, the three-electrode configuration of claim 31 does not measure the impedance of tissue between the electrodes. Therefore, modifying Pearlman to use a three-electrode configuration, as recited in claim 31, would result in a system that does not detect the presence of tumors, and therefore renders Pearlman unsatisfactory for its intended use.

Masuo would also be rendered unsatisfactory for its intended use. As discussed above, Masuo monitors fat content using a four-electrode technique that measures the impedance of subcutaneous tissue. As described above, Masuo uses two, non-current carrying measurement electrodes to eliminate impedance contributions due to the electrode-to-skin interface. (Masuo at ¶ 0005.) (Alternatively, Fig. 3 of Masuo subtracts the voltage V1 and V2 to estimate the same impedance measurement.) Modifying Masuo to use a three-electrode configuration would result in an isolated measurement of the impedance-to-skin interface – an electrical artifact that Masuo seeks to avoid, while yielding no information about the subcutaneous tissue (*e.g.*, fat content). Therefore, modifying Masuo to use a three-electrode configuration, as recited in claim 31, would render Masuo unsatisfactory for its intended use.

Because the modification of Bloom, Pearlman, or Masuo would render each respective reference unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification. Accordingly, Applicant submits it would not have been obvious to modify any one of the references to include the limitations of claim 31.

## CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 529552000100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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